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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0887; FRL-9388-1]

Propamocarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of propamocarb in or on succulent lima bean. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2008-0887, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: *nollen.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To

access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2008-0887 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2008-0887, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 13, 2009 (74 FR 16866) (FRL-8396-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7473) by IR-4, Rutgers University, 500 College Rd. East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.499 be amended by establishing a tolerance for residues of the fungicide propamocarb hydrochloride (propamocarb HCl), propyl[3-(dimethylamino)propyl]carbamate monohydrochloride, in or on succulent lima bean at 2.0 parts per million (ppm). That document referenced a summary of the petition prepared on behalf of IR-4 by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for propamocarb including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with propamocarb follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and

children.

In all species tested for toxicity to propamocarb, decreased body weights, body-weight gains, and food consumption were observed following subchronic and chronic durations of exposure. Effects indicative of toxicity were noted in the digestive and gastrointestinal (GI) tracts in dogs, including chronic erosive gastritis and vacuolization of the salivary glands, stomach, and duodenum. Ocular effects were noted in rats (opacity of the eye and yellow colored eyes in females) and in dogs (vacuolization of the lacrimal gland, retinal degeneration, and hyporeflectivity of the inner eye tissue below the lens). Respiratory tract effects were also noted in dogs, including vacuolization of the cells of the trachea and lung. In rats, there were signs of neurotoxicity including decreased motor activities in females following acute exposure and vacuolization of the ventricles of the brain that produce cerebral spinal fluid noted for subchronic and chronic durations. There were no signs of immunotoxicity in the guideline immunotoxicity study for propamocarb.

Fetal effects due to propamocarb treatment were noted at doses which also caused maternal toxicity. Effects in the rat included increased fetal death and post-implantation loss, increases in minor skeletal anomalies, and increased incidences of small fetuses. There were also inter-atrial septal defects, and hemorrhage in the ears, upper GI tract, and nasopharynx/sinuses. Maternal effects consisted of decreased absolute body weights, body-weight gains and food consumption, and mortality. In rabbits, the only developmental effect was an increase in post-implantation loss. Maternal effects consisted of increased abortions, and body-weight decrements.

Additionally, in the rat 2-generation reproduction studies, parental and offspring effects occurred at the same dose. Parental effects were similar to the effects observed in

the rat subchronic and chronic studies in addition to clinical signs including salivation, reddish material around the mouth, and urine staining. Offspring effects consisted of pup deaths, decreased viability and lactation indices and litter size, and decreased pup body weights and body weight gains. Reproductive effects consisted of increased vacuolization and decreased weight of the epididymides, decreased sperm counts and motility, and abnormal sperm morphology.

Propamocarb has been classified as "not likely to be carcinogenic to humans" by all routes of exposure, based upon lack of evidence of carcinogenicity in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by propamocarb as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document entitled "Propamocarb Hydrochloride (Propamocarb-HCl). Section 3 Request for use on Lima Beans (Succulent). Human-Health Risk Assessment**"** at pp. 32-37 in docket ID number EPA-HQ-OPP-2008-0887.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in

conjunction with the POD to calculate a safe exposure level--generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)--and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for propamocarb used for human-health risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Propamocarb for Use in Human Health Risk Assessment

Exposure/Scenario	**POD and UFs/SFs**	**RfD, PAD, LOC for Risk Assessment**	**Study and Toxicological Effects**
Acute dietary (Females 13-49 years of age)	NOAEL = 150 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 1.5 mg/kg/day aPAD = 1.5 mg/kg/day	Developmental Toxicity Study - Rabbit LOAEL = 300 mg/kg/day based on decreased body weight gain and decreased motor activity.

Acute dietary (General population including infants and children)	NOAEL = 200 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 2 mg/kg/day aPAD = 2 mg/kg/day	Acute Neurotoxicity Screening Battery - Rat LOAEL = 2,000 mg/kg/day based on decreased body weight gain and decreased motor activity.
Chronic dietary (All populations)	NOAEL= 12 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.12 mg/kg/day cPAD = 0.12 mg/kg/day	Carcinogenicity Study - Mouse LOAEL = 95 mg/kg/day based on decreased body weight and body weight gain in females.
Dermal short-term (1 to 30 days)	Dermal (or oral) study NOAEL = 150 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	2-Generation Reproduction Toxicity Study – Rat LOAEL = 406.69 mg/kg/day for males and 467.13 mg/kg/day for females based on decreased body weights.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans."		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). POD = points of departure. RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to propamocarb, EPA considered exposure under the petitioned-for tolerances as well as all existing propamocarb tolerances in 40 CFR 180.499. EPA assessed dietary exposures from propamocarb in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for propamocarb. In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA), conducted from 2003-2008. As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all commodities. In addition, DEEM version 7.81 default processing factors were used, when appropriate.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used DEEM-FCID Version 3.16. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues for all commodities. In addition, DEEM version 7.81 default processing factors were used, when appropriate.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that propamocarb does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for propamocarb. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for propamocarb in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of propamocarb. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of propamocarb for surface water are estimated to be 8,762 parts per billion (ppb) for acute exposures and 1,067 ppb for chronic exposures for non-cancer assessments. For ground water, the EDWC is estimated to be 15.6 ppb for acute and chronic exposures for non-cancer assessments.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 8,762 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1,067 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Propamocarb is currently registered for use on golf course turf, which may result in residential exposure. EPA assessed residential exposure using the following assumptions: Chemical-specific turf transferable residue (TTR) data for propamocarb were used to assess potential short-term dermal post-application exposures to adult and youth golfers. Post-application oral and inhalation exposures, as well as residential handler exposures, are not expected based on the current use patterns for propamocarb. Intermediate-term residential exposures are not expected based on the current use patterns; however, the short-term aggregate assessment would be protective of any potential intermediate-term exposures, as the short- and intermediate-term PODs are the same. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have

a common mechanism of toxicity." Although a carbamate, propamocarb is not an *N*-methyl carbamate and does not cause cholinesterase inhibition. Therefore, it was not included in the *N*-methyl carbamate cumulative risk assessment. EPA has not found propamocarb to share a common mechanism of toxicity with any other substances, and propamocarb does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that propamocarb does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no increased quantitative prenatal sensitivity due to propamocarb treatment. Effects in developing rats occurred at the same dose as maternal effects and included increased fetal death and post-implantation loss, increases in minor skeletal anomalies, and an increased incidence of

small fetus. Effects in maternal rats at that dose consisted of decreased absolute body weights, body weight gains, food consumption, and mortality. In rabbits, the only developmental effect was an increase in post-implantation loss in the presence of maternal effects (increased abortions, and body weight decrements). In the rat 2-generation reproduction studies, parental effects were similar to the effects observed in the rat subchronic and chronic studies, in addition to clinical signs including salivation, reddish material around the mouth, and urine staining. Offspring effects consisted of pup deaths, decreased viability and lactation indices and litter size, and decreased pup body weights and body weight gains. Reproductive effects at the same dose as parental effects consisted of increased vacuolization and decreased weight of the epididymides, decreased sperm counts and motility, and abnormal sperm morphology.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for propamocarb is complete.

ii. There are two guideline acute neurotoxicity studies and two subchronic neurotoxicity studies for propamocarb HCl. The effects of these studies are well characterized, and include decreased motor activities in females following acute exposure. However, the endpoints selected are protective of these effects, as the rat acute oral neurotoxicity study was used to select the endpoint for the aRfD of 2.0 mg/kg/day for the general U.S. population, including infants and children. The lack of quantitative increased fetal sensitivity should remove concern for a developmental neurotoxicity study (DNT).

iii. There is no evidence that propamocarb results in increased quantitative susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Although there are qualitative effects observed in both developmental studies, as well as in one of the 2-generation reproduction studies, EPA has determined that no additional UF is necessary to account for these effects because:

a. The effects are well characterized.

b. Clear NOAELs were established.

c. The developmental rabbit and rat 2-generation reproduction studies are being used in endpoint selection.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to propamocarb in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children. Incidental oral exposure is not expected for children. These assessments will not underestimate the exposure and risks posed by propamocarb.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring

cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposures, the acute dietary exposure from food and water to propamocarb will occupy 34% of the aPAD selected for females 13-49 years old; and 75 % of the aPAD for infants less than 1 year old, the population group receiving the greatest exposure for the general U.S. population, including infants and children.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to propamocarb from food and water will utilize 50% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of propamocarb is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Propamocarb is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to propamocarb.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 310 for adult male golfers, 280 for golfers aged 11 to less than 16

years old, and 240 for golfers aged 6 to less than 11 years old. Because EPA's level of concern for propamocarb is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however**,** propamocarb is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for propamocarb**.**

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, propamocarb is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to propamocarb residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate gas chromatography with nitrogen-phosphorus detection (GC/NPD) method (Analytical Method No. XAM-34) is available to enforce tolerance expression on

plant commodities. The method may be found in the Pesticide Analytical Method (PAM) Vol. II.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for propamocarb.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the tolerance expression to clarify that:

1. As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of propamocarb not specifically mentioned.

2. Compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of propamocarb (propyl *N*-[3-(dimethylamino)propyl]carbamate) in or on bean, lima, succulent at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 28, 2013.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.499, revise the section heading, paragraph (a) introductory text, and paragraph (c) to read as follows:

§ 180.499 Propamocarb; tolerances for residues.

(a) *General*. Tolerances are established for the residues of propamocarb, including its metabolites and degradates, in or on the commodities specified in the following table resulting from the application of the hydrochloride salt of propamocarb. Compliance with the following tolerance levels is to be determined by measuring only propamocarb (propyl *N*-[3-(dimethylamino)propyl]carbamate):

* * * * *

(c) *Tolerance with regional registrations*. Tolerances with regional registrations are established for the residues of propamocarb, including its metabolites and degradates, in or on the commodities specified in the following table resulting from the application of the hydrochloride salt of propamocarb. Compliance with the following tolerance levels is to be determined by measuring only propamocarb (propyl *N*-[3-(dimethylamino)propyl]carbamate):

Commodity	Parts per million
Bean, lima, succulent	2.0

* * * * *

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